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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,553	01/11/2002	Scott B. Kokones	P-10289.00	1834
27581	7590	05/18/2004	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			MACHUGA, JOSEPH S	
			ART UNIT	PAPER NUMBER
			3762	10

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/045,553	KOKONES ET AL.
	Examiner	Art Unit
	Joseph S. Machuga	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on Feb. 23, 2004.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-21 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

***Response to Amendment***

Applicant's comments regarding the rejection under 35 USC 112 first paragraph are greatly appreciated. However it is still not clear how the gripper operates. Specifically the structure appears to be solid and inflexible but the term gripper used to describe the component infers some form of mechanical movement. The citations given do not clarify this.

Applicants arguments with regard to the rejection under 35USC 103 are considered moot based on the new grounds of rejection.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is not clear from the specification how the style handle grips and releases the lead body. Clarification is needed.

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3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The language "one or more indentations" is confusing. The term "indentation" infers the existence of a recess rather than a projection and therefore would not "extend" into the channel. Clarification is needed.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duysens et al (#6104960) in view of Borkan (#6510347) and Auth (#4829999.)

3. Duysen et al disclose a neurological implant system for locating an electrode in a patient adjacent the spinal column. The device includes as illustrated in Figure 7

includes an electrode, stylet wire and a handle 170 for gripping the electrode and wire.

Not disclosed by this reference are the specifics of the electrode and the handle claimed.

4. Borkan discloses a spinal cord stimulating lead having electrodes (34, 36), electrical connector (39), an internal conductor joining those two elements, and a stylet wire. In some embodiments the electrode is closed and would form a stop for the wire. This design of an electrode helps conserve power.

5. Auth discloses a device for gripping a medical lead having a lead carrier (12), a lead gripper(18,20) and release mechanism (22, 24.) The device has an open construction that allow it to grip the wire along any point of its length. The surface of portion (18, 20) includes a high friction surface deposited thereon. This structure would create a surface having a large number of very small recesses and projections.

6. Given these references, it would have been obvious to one of ordinary skill in the art to use an electrode of the type disclosed by Borkan in place of the electrode in Duyden et al device to provide a more efficient system. To use a feed of the type disclosed by Auth in place of that disclosed by Duysen et al would have also been obvious given that it provides better control of the elements. Also, while the Borkan reference does not explicitly state that the internal conductor is insulated it is considered obvious that it is since in some embodiments fluid is introduced into the lumen.

Finally, to insert the stylet into the lead/lumen before placing it in the holder is considered one of two possible and obvious methods of use. The other being inserting the stylet into the lead/lumen after it's in the holder.

7. Claims 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duysens et al (#6104960) in view of Borkan (#6510347) and Auth #4829999 as applied to claims 1-16 above, and further in view of Pillari #4834708.

Pillari discloses a needle assembly having projections 64 that create a frictional surface on the device. Given Pillari's disclosure it would have been obvious to one of ordinary skill in the art to add projections in place of roughened surface (18,20) of Auth's device to provide a more defined frictional surface.

8. Claims 1-3, 5-7, 9-17 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duysens et al (#6104960) in view of Borkan (#6510347) and Loney et al (#5137517.)

9. Duysen et al disclose a neurological implant system for locating an electrode in a patient adjacent the spinal column. The device includes as illustrated in Figure 7 an electrode, stylet wire and a handle 170 for gripping the electrode and wire. Not disclosed by this reference are the specifics of the electrode and the handle claimed.

10. Borkan discloses a spinal cord stimulating lead having electrodes (34, 36), electrical connector (39), an internal conductor joining those two elements, and a stylet wire. In some embodiments the electrode is closed and would form a stop for the wire. This design of an electrode helps conserve power.

11. Loney et al discloses a device for gripping a medical lead having a lead carrier and means to grip (16) the lead body at any point along the lead body.

12. Given these references, it would have been obvious to one of ordinary skill in the art to use an electrode of the type disclosed by Borkan in place of the electrode in Duyden et al device to provide a more efficient system. To use a feed of the type disclosed Loney et al in place of that disclosed by Duysen et al would have also been obvious given that it provides better control of the elements. Also, while the Borkan reference does not explicitly state that the internal conductor is insulated it is considered obvious that it is since in some embodiments fluid is introduced into the lumen. Finally, to insert the stylet into the lead/lumen before placing it in the holder is considered one of two possible and obvious methods of use. The other being inserting the stylet into the lead/lumen after it's in the holder.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

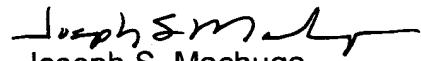
§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Joseph S. Machuga  
Examiner  
Art Unit 3762

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ANGELA D. SYKES  
SUPERVISORY PATENT EXAMINER  
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